UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,868	11/26/2002	Xue Mei Zhou	3291.3B	5269

22886 7590 02/10/2005

AFFYMETRIX, INC
ATTN: CHIEF IP COUNSEL, LEGAL DEPT.
3380 CENTRAL EXPRESSWAY
SANTA CLARA, CA 95051

EXAMINER	
MILLER, MARINA I	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/065,868	ZHOU ET AL.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *36-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35 and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/07/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (claims 1-35 and 84 directed to a method, a system, and a genomic portal system for providing custom probe array) filed on 1/07/2005 is acknowledged. Applicant's election of specie A, nucleic acids; specie B, uniqueness; specie C, one or more indicators of geographic dispersion of probe sets on the probe array; and specie D, a gene, is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 36-83 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

An action on the merits of claims 1-35 and 84, as they read on the elected species, follows.

Priority

Applicant's claim for priority under 35 U.S.C. 119(e), 120, and 122 is acknowledged. However, the application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-32 and 84 of the instant application.

Applicant claims priority to a series of provisional, non-provisional, and PCT applications. Examiner thoroughly reviewed all priority application. None of the priority applications provide support for elected claims 1-35 and 84 of the instant application drawn to a method and a system for providing custom arrays. The priority applications do not disclose a method comprising steps of receiving probe identifiers, determining verified probe sets, generating a probe array design, enabling for display, and providing a

probe array, as recited in claims 1 and 84. These applications also do not provide support for a system or a genomic portal system, as in claims 19-32 and 33-35, comprising means/instructions for performing steps similar to those of claims 1-35 and 84. As none of the priority applications provide support for the instant claims, priority for the elected claims is granted only to the filing date of the instant application, filed 11/26/2002. If applicant desires benefit of one or more priority applications, applicant is invited to point to specific support by page and line number for each limitation of the instant claims in each priority application.

Information Disclosure Statement

The information disclosure statement filed 12/17/2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the following publications listed on the IDS have not been filed: WO 01/31333A1, WO 01/80155A2, WO 02/061646A1, and JP 2002074089. There is no evidence of record that these references were filed with the IDS.

To expedite prosecution, examiner retrieved publications WO 01/31333A1 and WO 01/80155A2. Consideration of these references is indicated by the examiner's initials. Any references not considered by the examiner have been crossed out. The examiner's signature on the IDS indicates consideration of only the initialed citations.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with

the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 101

Lack of Utility

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3-35, and 84 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The specification discloses that utility for the claimed invention is a use of microarray data to study genetic characteristics and detect diseases. In particular, to detect what genes are expressed in particular tumors, organs, tissues, or species and how different factors influence gene expression (*see* p. 3 of the specification). However the disclosed utility is not applicable to the instant claims. For example, the result of the claimed methods is providing/enabling a probe array which is determined on the basis of an unknown probe set identifier. In order for the result of the method to be used for diagnostic purposes, one skilled in the art must be aware of a correlation between the information retrieved from the method and a disease, disorder, or condition to be diagnosed. No such correlation is recited in the instant claim; further research would be required to determine such a correlation. Applicant is reminded that a "use" to perform further research is not a utility under 35 U.S.C. 101. In the absence of recitation of specific probe identifiers (*e.g.*, tissues, cells, sequences, codes, etc., known to be

correlated to a disease, disorder, or condition for diagnosis), or recitation of specific genetic information with a similar correlation (*e.g.*, haptotype frequency, SNP, splice variants, etc. known to be associated with a disease or propensity for disorder/disease), the claims do not provide an "immediate benefit" to the public, and lack utility.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-35 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson, WO 01/80155.

Anderson discloses a method for a custom biological array design, similar to the method of instant claim 1. Steps of the method are disclosed by Anderson in Example 7 (p. 22-24): receiving a user selection of probe identifier (step 1 in example 7) wherein a user communicates his selection via a communication network, p. 8, line 32-33-p. 9, line 1-25 and p. 13, line 7-14; determining probe sets corresponding to the probe identifier, p. 23, line 28-32, generating a probe array design (step 2 in example 7); enabling for display

via graphical interface, p. 24, line 9-14; and providing a probe array constructed to detect nucleic acids (step 3 in example 7 and p. 23, line 12-25). Thus, Anderson anticipates instant claim 1. Anderson also discloses an array to diagnose a medical condition, p. 1, line 24-28 and p. 10, line 31-33, thus anticipating instant claim 2. Anderson discloses a spot and synthesized probe array, p. 11-12 (Fabricating Oligonucleotide Arrays) and p. 14, line 2-4, thus anticipating instant claim 3. Anderson discloses a probe array capable of hybridizing with biological molecules, p. 23, line 12-27 and p. 24, line 21-26, thus anticipating claim 4.

Anderson also discloses steps of a method similar to the method recited in instant claim 5 (example 7), *i.e.*, receiving a probe identifier, determining a probe set, generating a probe array, enabling for display, providing the probe array to a user, thus anticipating claim 5. Anderson discloses a user communicating his selection via the Internet, p. 11, line 11-16, thus anticipating instant claim 6. Anderson discloses a probe set identifier comprising sequence information, p. 5, line 27-33-p. 6, line 20 and p. 23, line 12-25, thus anticipating claim 7. Anderson discloses selection of a probe identifier from a predetermined list, (p. 23, line 24-25 (GenBank) and fig. 3a), thus anticipating instant claims 8 and 9. Anderson discloses a probe set determined on the basis of uniqueness, [p. 23, line 19-25 (specific mutations)], thus anticipating instant claim 10. Anderson discloses an act of generating array based on format factor and an act of receiving user-selected probe array format factors, p. 19, line 31-33-p. 20, line1-3 and p. 24, line 1-8, thus anticipating instant claims 11 and 12. Anderson discloses probe array factors as being indicators of geographic locations, p. 11-12 (Fabricating Oligonucleotide Arrays), thus anticipating claim 13. Anderson discloses substrate material as being glass, p. 5, line

15-18, thus anticipating claim 14. Anderson discloses an act of generating comprising modifying by user, p. 24, line 1-8, thus anticipating claim 15. Anderson discloses a graphical user interface over a network, p. 14, line 21-33-p. 15, line 1-5 and p. 23, line 3-11, thus anticipating claim 16. Anderson discloses an act of determining and enabling (p. 24, line 1-8 and fig. 1), similar to steps recited in instant claim 17, thus anticipating claim 17. Anderson discloses a spot and synthesized probe array, p. 11-12 (Fabricating Oligonucleotide Arrays) and p. 14, line 2-4, thus anticipating instant claim 18.

Anderson discloses a system for providing a custom probe array, similar to the system recited in instant claim 19. Anderson's system comprises: an input manager and a gene verifier, p. 14, line 21-33-p. 15, line 1-5 and p. 24, line 1-8 and p. 23, line 3-11; a probe generator, p. 24, line 1-8; and a user processor comprising a user interface (p. 14, line 21-33-p. 15, line 1-5 and p. 24, line 1-8) and providing for an array (p. 24, line 15-17), thus anticipating claim 19. Anderson discloses a user selection that is received via the Internet, p. 14, line 21-33-p. 15, line 1-5 and p. 23, line 3-11, thus anticipating claim 20. Anderson discloses a probe set identifier comprising sequence information, p. 5, line 27-33 and p. 23, line 12-25, thus anticipating claim 21. Anderson discloses selection of a probe identifier from a predetermined list, (p. 23, line 24-25 (GenBank) and fig. 3a), thus anticipating instant claims 22 and 23. Anderson discloses a probe set determined on the basis of uniqueness, [p. 23, line 19-25 (specific mutations)], thus anticipating instant claim 24. Anderson an array generator based on format factor and an impute manager receiving user-selected probe array format factors, (p. 19, line 31-33-p. 20, line1-3 and p. 24, line 1-8), thus anticipating instant claims 25 and 26. Anderson discloses probe array factors as being indicators of geographic locations, p. 11-12 (Fabricating Oligonucleotide

Arrays), thus anticipating claim 27. Anderson discloses substrate material as being glass, p. 5, line 15-18, thus anticipating claim 28. Anderson discloses a generator constructed to modify format factors by user, p. 24, line 1-8, thus anticipating claim 29. Anderson discloses a graphical user interface over a network, p. 14, line 21-33-p. 15, line 1-5 and p. 23, line 3-11, thus anticipating claim 30. Anderson discloses a gene verifier and a user data processor, p. 24, line 1-8 and fig. 1, thus anticipating claim 31. Anderson discloses a spot and synthesized probe array, p. 11-12 (Fabricating Oligonucleotide Arrays) and p. 14, line 2-4, thus anticipating instant claim 32.

Anderson discloses a genomic portal system for providing custom probe array, similar to the system recited in instant claim 33. Anderson's system comprises: an input manager and a gene verifier (p. 14, line 21-33-p. 15, line 1-5 and p. 24, line 1-8 and p. 23, line 3-11), a generator (p. 24, line 15-17), a data processor (p. 14, line 21-33-p. 15, line 1-5 and p. 24, line 1-8 and p. 23, line 3-11), and a network comprising output manager (p. 15, line 24-33); *see* also fig. 1 and (p. 8, line 24-33-p. 9, line 26). Thus, Anderson anticipates claim 33. Anderson also discloses a network server receiving a user input and a user computer enabled for selection (p. 14, line 21-33-p. 15, line 5), thus anticipating claim 34. Anderson discloses an output manager (p. 15, line 24-33 and p. 24, line 9-14), similar to the one recited in instant claim 35, thus anticipating claim 35.

Anderson discloses steps of the method, similar to the method recited in instant claim 84, comprising: receiving probe set identifier, determining probe sets, generating a design, and providing a probe array, *see* example 7. Thus Anderson anticipates claim 84.

Claims 1, 3, 5-8, 11-13, 15-22, 25-27, 29-35, and 84 are rejected under 35 U.S.C. 102(a) as being anticipated by Tekagawa, WO 02/61646.

The US published application, US 2004/067488, was filed as a National stage application of PCT/JP01/00683, and is therefore the English translation of WO 02/61646. To facilitate examination, references below are made to US 2004/067488.

Tekagawa discloses a method for providing a DNA chip, similar to methods recited in instant claims 1 and 2. Steps of the methods, *i.e.*, receiving (fig. 3), determining and generating (fig. 4), enabling (fig. 5), and providing (fig. 34), are generally discloses in [0055 and 59].

Tekagawa discloses a system comprising: an input manager, a receiving system, and a user data processor. Tekagawa's receiving system (fig. 1) accepts information related to a DNA chip such as an arrangement of probes having particular sequences and the probe properties [0055-58, 0100, and 0121-22], thus anticipating claim 19

Tekagawa discloses a spot array, fig 34, thus anticipating claims 3, 18, and 32. Tekagawa disclosed the user selection as being received via Internet, [0017, and fig. 1, element 100], thus anticipating claims 6 and 20. Tekagawa discloses a probe set comprising sequence information, fig. 4, thus anticipating claims 7 and 21. Tekagawa discloses selection of a probe identifier from a predetermined list, fig. 7-8, thus anticipating claims 8 and 22. Tekagawa discloses array based on format factors selected by a user, fig. 4-5, 8, and 9, thus anticipating claims 11-12 and 25-26. Tekagawa discloses probe array format factors including indications of geographic dispersion, [0117] and fig. 31, thus anticipating claims 13 and 27. Tekagawa discloses modification by a user format factors, fig. 8-10. Tekagawa discloses a user interface as being provided

via a network, [0057] and fig. 1, thus anticipating claims 16 and 30. Tekagawa discloses a method and a system, similar to that in instant claims 17 and 31 wherein steps of determining and enabling are disclosed by Tekagawa in [0059] and fig. 8-10.

Tekagawa discloses a genomic portal system for providing a probe array comprising: an input manager (fig. 1 and [0057]); a receiving system (*see* above, p. 9) [0055-58, 0100, and 0121-22]; a probe generator (fig. 4); a data processor, (fig. 8-10); and a network ([0057]). General description of the portal is discloses in fig. 1. Thus, Tekagawa anticipates claim 33. Tekagawa discloses a network server comprising an input device and a user computer, fig. 1, thus anticipating claim 34. Tekagawa discloses an output manager, fig. 34, thus anticipating claim 35.

Tekagawa discloses steps of the method similar to instant method of claim 84: receiving, determining, generating, and providing, [0059], thus anticipating claim 84.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 4, 14, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tekagawa, WO 02/61646, as applied to claims 1, 3, 5-8, 11-13, 15-22, 25-27, 29-35, and 84 above, in view of Cantor, U.S. Patent 6,007,987.

Tekagawa teaches the method of claim 1 and the system of claim 19, as recited above.

Tekagawa does not disclose a probe array constructed to diagnose disease or a probe array capable of hybridizing with biological material, recited in instant claims 2 and 4. Takegawa also does not disclose a substrate material such as resins or gels, recited in instant claims 14 and 28.

Cantor discloses a probe array constructed to diagnose disease or for hybridizing with biological material, col.16, lines 10-31. Cantor also discloses resin and gel supports, col. 13, line 38-39.

It would have been obvious to one skilled in the art at the time of the invention to modify the method and the system of Tekagawa to use a probe array bound to a support for diagnosis or hybridization with biological material, such as taught by Cantor, where the motivation would have been to improve detection of clinically important samples, as taught by Cantor, *see* Description of the Background, col. 1-3.

Claims 8-10 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tekagawa, WO 02/61646, as applied to claims 1, 3, 5-8, 11-13, 15-22, 25-27, 29-35, and 84 above, in view of Garner, U.S. 2003/0033290.

Tekagawa teaches the method of claim 1 and the system of claim 19, as recited above.

Tekagawa does not disclose a probe set identifier selected from a list of genes, as recited in instant claims 14 and 28. Tekagawa does not disclose a probe set determined on the basis of "uniqueness," as recited in the instant claims 10 and 24.

Garner discloses a sequences from a database comprising sequence identifiers corresponding to genes, similar to instant claims 9 and 23, and a selection based on accession number, similar to instant claims 10 and 24.

It would have been obvious to one skilled in the art at the time of the invention to modify the method and the system of Tekagawa to use a probe array based on unique genomic sequence, such as taught by Garner, where the motivation would have been to apply microarray technology to studying expression pattern of genes, as taught by Garner, [0005].

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. U.S. Patent No. 5,545,531 (disclosing a solid addressable array).

2. U.S. Patent No. 6,180,351 (disclosing generation of an array, array layout, an identifier, and a system for generating an array).

3. US 2002/0048763 (disclosing an array and a system for generating an array).

4. US 2002/0102559 (disclosing an array, an identifier, a method for generating an addressable array, a computer system for generating an array).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller
Examiner
Art Unit 1631

mm

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran
2/7/05